MAY - 6 2005

LASER SYS*STIM® 540
MODEL ME 540
510(K) SUMMARY STATEMENT [K(TBD)]

K043586

Submitter's Name: Mettler Electronics Corp.
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Contact: Rob Fleming, Regulatory Compliance Manager
and Official Correspondent
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Date Prepared: December 22, 2004

Device Name:

a. TRADE NAME:	Laser Sys*Stim 540, Model ME 540
b. CLASSIFICATION NAME:	Infrared Lamp
c. COMMON NAME:	Low Level Laser Therapy (LLLT)

Predicate Devices:

In our opinion, the Laser Sys*Stim® 540, Model ME 540, is substantially equivalent to other infrared therapeutic lamps that are currently in commercial distribution. These predicate devices include the MedX 1100 Console (K032231), Dynatronics' Solaris D890 Therapy Probe (K040729) and Dynatronics' Solaris D880 Infrared Probe (K031329).

Description of Device:

The Laser Sys*Stim 540, Model ME 540, is a portable, AC and battery operated non-invasive, low level infrared lamp that provides continuous and pulsed heat therapy at a fixed frequency. The system consists of a drive unit/power supply that houses the electronics, controls and displays and optional treatment probes that contain the visible and infrared radiating elements.

LASER SYS*STIM® 540
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Device Intended Use Statement:

510(k) Number: TBD

Device Name: Laser Sys*Stim, Model ME 540

Indication for use: The Laser Sys*Stim, Model ME 540, is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, the temporary increase in local blood circulation and/or promoting relaxation of muscles.

Comparison of Technological Characteristics Between ME 540 and Predicate Devices:

The Laser Sys*Stim, Model ME 540, and predicate devices listed above, are infrared lamps as defined in 21 CFR 890.5500 using infrared and visible laser diodes that generate topical heating for the purpose of elevating tissue temperatures for temporary relief of muscle and joint pain.

Testing:

Production and quality control performance and safety testing shall be performed on each system pursuant to compliance with all applicable safety standards and regulations for low level laser therapy systems.

Conclusion:

The Laser Sys*Stim, Model ME 540, is substantially equivalent to, and shares the same indications for use, general technical characteristics and user interface controls as, the listed predicate devices. It is designed to provide topical heating in the infrared and visible wavelength spectrum at energy levels previously found acceptable by the Food and Drug Administration. Each unit shall undergo compliance verification testing prior to introduction into interstate commerce to insure conformance to specifications and applicable safety standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 6 2005

Mr. Robert E. Fleming
Regulatory Compliance Manager
Mettler Electronics Corporation
1333 South Claudina Street
Anaheim, California 92805

Re: K043586
Trade/Device Name: Laser Sys*Stim 540, Model ME 540
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: March 9, 2005
Received: March 10, 2005

Dear Mr. Fleming:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043586

Device Name: Laser Sys*Stim 540, Model ME 540

Indications for Use:

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Prescription Use ___X___ AND/OR Over the Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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K043586